Human Subject Research Ramp Up Guidance Table

This table identifies person-to-person HSR study activities *(in-person interactions, interventional activity or procedure)* allowable under each research activity category[1] described in the VPR Research Ramp Up Planning document. Researchers are encouraged to use this table to evaluate their study activities to determine under which research activity category their study would be allowed to restart.

Restarting of any person-to-person HSR study will be based on the ability to abide by current COVID-19 restrictions in place and the risk for exposure or transmission as it relates to the in-person interaction, interventional activity, or procedure necessary to conduct the study.

HSR studies that require modifications to a MTU-IRB approved protocol need to submit an amendment package to IRBNet for review and approval. Along with any protocol modifications, research teams will need to develop plans to implement *HSR Ramp Up Additional COVID-19 Requirements* (see page 2) and submit them to irb@mtu.edu for COVID-19 Committee review and approval.

Please remember these are guidelines and and meant to provide a starting point to assess HSR studies in preparation for ramp up.

Research Activity Category[1]	HSR Person-to-Person Study Activities Allowed	State of Michigan Restrictions in Place	IRBNet Amendment Package Needed?	Additional HSR COVID-19 Requirements	COVID-19 Committee Approval to restart?
Exempt Essential Covid-19 Response Critical High Level[3]	• Studies conducted via virtual, electronic, or online methods • Data analysis of data collected prior to pause of an active study • Secondary use of data (retrospective) **Examples Activities:** Online surveys, virtual interviews and focus groups	• SHSS • Strict social distancing[2] • Face coverings • No gatherings	Yes, if protocol requires modifications to conduct research under COVID-19 restrictions.	NA	NA
Medium Level[3]	• In-person interaction, interventional activities, and procedures that can maintain social distancing[2] • Activities or procedures completed in a single brief visit (2hr or less) • Can be conducted with limited number of research team members (max 2) • Healthy, 65 or younger, and not at higher risk for severe illness from COVID-19[4] **Examples Activities/Procedures:** Non-invasive procedures[6] and behavioral interventions, eye-tracking, computer tasks, DEXA scan ***No procedures or activities involving direct physical contact with participant (including to instrument them for a test) is allowed at this level.***	• Safer at Home • Social distancing[2] • Face coverings • Small gatherings	Yes, if protocol requires modifications to conduct research under COVID-19 restrictions.	• COVID-19 training • Research team and participant COVID-19 screening • Social distancing plans • Face coverings • Increased disinfecting procedures[5] • Research activity tracking • Participating in HSR & COVID-19 • Contingency plans	Yes
Lower Level[3]	• In-person interaction, interventional activities and procedures that can maintain social distancing[2] **or** be performed while wearing face coverings and gloves • Multiple visits allowed if non-sensitive timeline[7] • Can be conducted with limited number of research team members (max 2) • Healthy, 65 or younger, and not at higher risk for severe illness from COVID-19[4] **Example Activities/Procedures:** Blood or urine collection, blood pressure measuring, non-sweat inducing procedures and testing, balance testing	• Stay Safe • Social distancing[2] • Increased size gatherings	Yes, if protocol requires modifications to conduct research under COVID-19 restrictions.	• COVID-19 training • Research team and participant COVID-19 screening • Social distancing plans • Face coverings & gloves • Increased disinfecting procedures[5] • Research activity tracking • Participating in HSR & COVID-19 • Contingency plans	Yes
Lowest Level[3]	Resume all HSR studies	NA	NA	NA	NA

[1]Institutional Activity Category requirements can be found in the Research Ramp Up Planning document.
[2]Social distancing, as defined by the CDC, must also correspond to any applicable institutional, state, or local restrictions in place.
[3]Level refers to COVID restrictions in place (i.e., SHSS, social distancing, face coverings, gatherings size, travel)
[4]Futher information regarding people at higher risk for severe illness from COVID-19 can be found in detail on the CDC website.
[5]For a list of disinfecting options and general laboratory guidance refer to the Ramping Up Research Checklist.
[6]Non-invasive means no break in the skin is created during procedure, no contact with mucosa, skin break, or internal body cavity.
[7]Non-sensitive timeline refers to projects that require participants return on a specific date or lose applicability of previously acquired data.

Human Subject Research Ramp Up Additional COVID-19 Requirements

Updated: June 29, 2020

Person-to-person HSR studies will begin to ramp up as COVID-19 restrictions (MTU, State, and local) lift and risks of exposure and transmission lessen. Researchers are encouraged to use the HSR Ramp Up Guidance Table, Flow Chart, and this document to best understand when their studies might be able to restart and be prepared to request approval at the earliest opportunity.

This document provides a checklist of all added HSR COVID-19 related requirements necessary to assist with mitigating exposure and transmission while conducting study protocols. Researchers should develop plans for implementing them and be prepared to share plans with a special COVID-19 Committee. The committee, comprised of representatives from human research protections, infections disease, and research laboratory operations will review study plans and grant final approval for studies to restart. Completed plans to incorporate these requirements can be sent to irb@mtu.edu. ***Please do not submit plans until the study activities are allowable within the current research activity category.***

Reminder, any modifications to approved MTU-IRB protocols should be submitted to IRBNet for review and approval PRIOR to submitting your request to restart research to the COVID-19 committee.

The following are minimum requirements needed in the HSR Ramp Up Plans submitted to the HSR COVID-19 Committee. The study PI is responsible to access each study re-starting to ensure plans are in place and to access if additional study specific requirements are needed. A HSR Ramp Up Plan template is now available for use to create plans for review by the HSR COVID-10 Committee.

☐ **COVID-19 TRAINING** (*UPDATED: June 29, 2020)*
All research team members must complete COVID-19 training. This training is now being administered through SafetySkills. Access to the training will be sent to each team member directly to complete by EHS. The PI is responsible for tracking and documentation of completion by all team members.

☐ **RESEARCH TEAM MEMBER AND PARTICIPANT SCREENING** *(UPDATED: June 29, 2020)*
The PI must establish a process required for daily health screenings of all research team members. At minimum, the use of the MTU COVID-19 Daily Symptom Monitoring Form available through the MTU Flex Portal for faculty, staff, and students must be completed daily by all research team members.

Participants will not be able to use the MTU COVID-19 Daily Symptom Monitoring Form. The PI must ensure participant screening prior to in-person interaction is completed. At minimum, the following screening information must be collected from any new or returning participants via phone, email, or other virtual method within 24 hours of the participants planned study-related visit or interaction and immediately before in-person interaction.

All screening information is considered private information that must be stored securely.

1. Heath screening needs to confirm participant is not a person at higher risk for severe illness from COVID-19. Refer to the CDC website for a complete list. In general, the following are at increased risk:
    - 65 years or older
    - People who live in a nursing home or long-term care facility
    - People at any age with underlying medical conditions

2. Questions relating to COVID-19 symptoms, possible exposures and travel.
    - Have you experienced any of the following symptoms (even if they were mild) in the past 14 days?
        - Cough
        - Shortness of breath or difficulty breathing
        - Fever
        - Chills
        - Muscle pain
        - Sore throat
        - New loss of taste or smell
    - Have you been in close contact[2] with any person experiencing symptoms or confirmed case of COVID-19?
    - Have you traveled the last two weeks? If so, to what locations?

Participants that report any symptoms of COVID-19 or possible exposure within the last 14 days are not permitted to participate in HSR research at MTU at this time.

☐ **TRAVEL** *(UPDATED: June 29, 2020)*

The PI (or designated team member) of the study is responsible for assessing any reported travel by the research team members or participants before and throughout an active HSR study. At minimum, any MTU Travel Restrictions should be enforced for both participants and research team members.

For HSR studies that require multiple visits, the PI is encouraged to consider requesting/requiring that any participant and research team member(s) agree to limit day-to-day activities to those that do not put them at high risk of potential COVID-19 exposure. For example, within a few days or week before the scheduled start of study and until the completion, participants and team members should avoid big crowds, visits to locations or with people from communities with higher COVID-19 cases, and situations where social distancing and face coverings are not able to be maintained.

☐ **RESEARCH TEAM MEMBER AND PARTICIPANT REPORTING** *(UPDATED: June 19, 2020)*

The following details must be included in the participant and research team member reporting procedures for this study. The study PI (or designated team member) should maintain the privacy of any person reporting symptoms or exposure.

- Research Team Members: In addition to reporting through the COVID-19 Daily Symptom Monitoring Form, a research team member experiencing symptoms or that becomes aware of direct contact with a known or possible positive case must report immediately to the PI (or designated team member) of the study.

- Participants: All participants will be instructed to report any symptoms of COVID-19 directly to the PI (or designated team member). They will also be informed to report any direct contact with a known or possible positive case that they become aware of within the 72 hours after each research activity.

- PI Responsibility: In the event of a reported exposure or symptoms, the PI (or designated team member) will pause any planned research activities scheduled for that day, temporarily close the laboratory, and immediately contact the HSR COVID-19 Committee via irb@mtu.edu or 7-1799. The PI (or designated team member) and Committee will work together to assess the situation and determine next steps.

☐ **SOCIAL DISTANCING PLANS**

Create social distancing[1] plans according to CDC guidelines and can be maintained by research team members and participants throughout the in-person interaction or visit. Be sure to think about shared laboratory spaces and limiting researchers in small spaces at one time in the plans.

☐ **FACE COVERINGS AND GLOVES**

Prior to restarting, procure all necessary face coverings and gloves, for research team members and participants, necessary to conduct the study. Research team members will be informed of proper face covering and glove use and disposal in their HSR COVID Training. PI's need to provide instruction of proper use to participants. The CDC also provides guidance on proper face coverings, use, and removal.

☐ **DISINFECTING AND CLEANING**

Refer to the Ramping Up Research Checklist for appropriate disinfecting methods. MTU custodial services is currently limited, refer the MTU Facilities Management webpage for details.

☐ **TRACKING RESEARCH ACTIVITY**

Develop a system to closely document laboratory activities than can be used to quickly identify any person impacted by a report of illness or exposure. Remember that any documentation accessible or visible to non-research team members must maintain participant confidentiality.

☐ **IMPLEMENT USE OF "PARTCIPATING IN HUMAN RESEARCH AND COVID-19"**

An informational document to be given to all potential participants prior to agreeing to participate will be provided to research teams when they receive approval to restart their research study. The document informs potential participants about COVID-19, the status of HSR at MTU, additional measures implemented to reduce risk of COVID-19 exposure, and their responsibilities if they choose to participate.

☐ **CONTINGENCY PLANS**

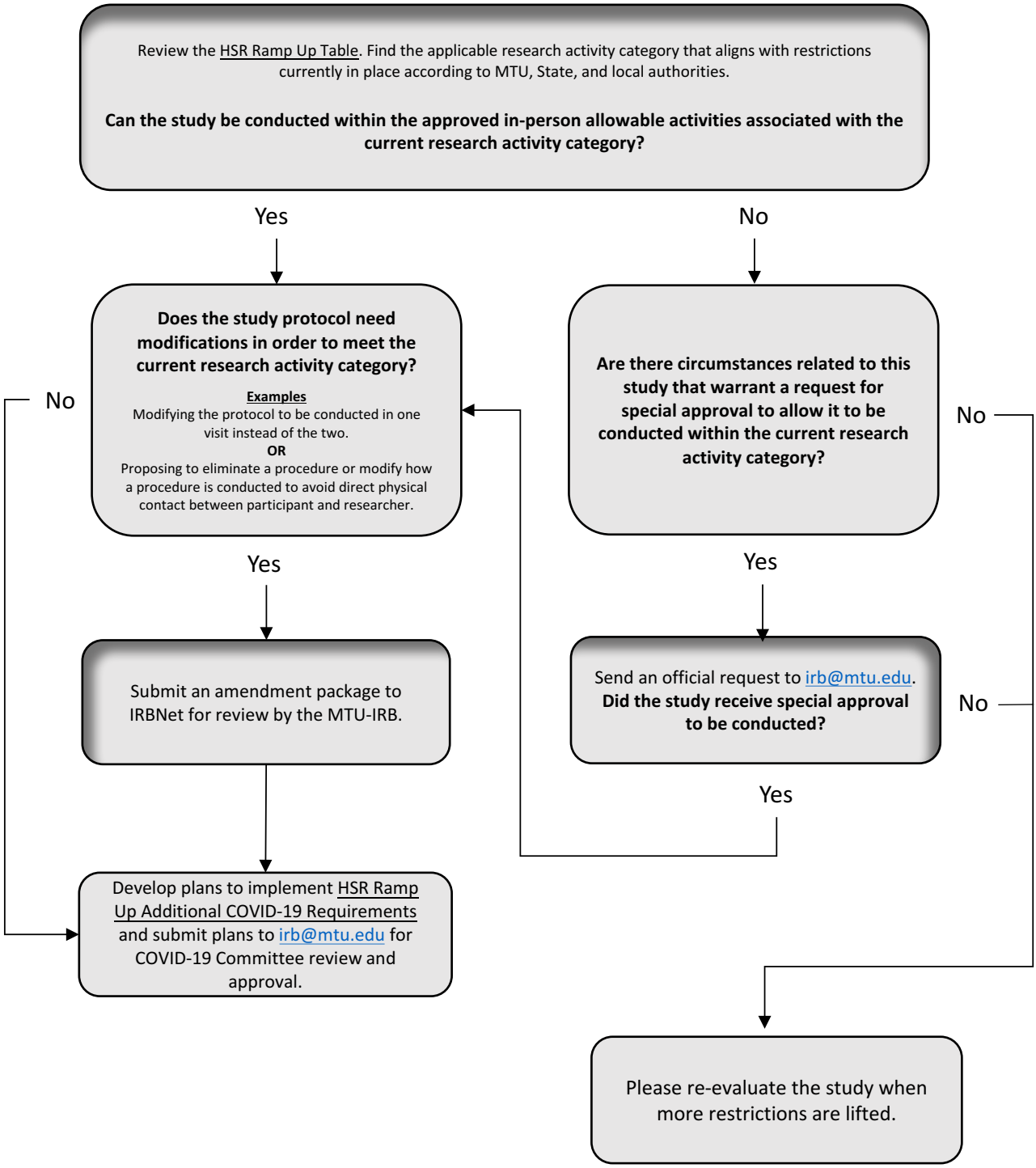
Given the uncertainty and evolving nature of the COVID-19 pandemic, it remains important for every research team to have a plan in place for additional closures, increased restrictions, or illness of essential team members/PI.

[1]*Social distancing is an intervention enacted to limit the spread of COVID-19. It includes reducing in-person contact between people to slow down the spread of the virus.*

[2]*Close contact is defined by the CDC as (a) being within approx. 6 feet (2 meters) of a COVID-19 case for a prolonged period of time. Close contact can occur while caring for, living with, visiting, or sharing a health care waiting area or room with a COVID-19 case OR (b) having direct contact with infectious secretions of a COVID-19 case (e.g., being coughed on).*

Human Subject Research Ramp Up Flow Chart

May 15, 2020



*Please Note: Review time will depend on the thoroughness of the submission and total amount of submissions waiting for review. After the COVID-19 Committee review is complete and approval is obtained, the study may restart.